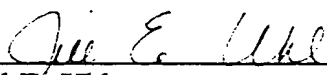


#4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Di Rienzo, et al.	)	I hereby certify that this paper and the
	)	documents referred to as enclosed
Serial No.: 09/251,274	)	herewith are being deposited with the
	)	United States Postal Service as First
Filed: February 16, 1999	)	Class Mail, postage prepaid, in an
	)	envelope addressed to: Assistant
For: METHODS FOR DETECTION	)	Commissioner for Patents,
OF PROMOTER POLYMORPHISM	)	Washington, D.C. 20231 on this date:
IN A UGT GENE PROMOTER	)	
	)	April 7, 1999
Group Art Unit: To be determined	)	
	)	Jill E. Uhl
Examiner: To be determined	)	Registration No: 43,213
	)	Attorney for Applicants

ESTABLISHMENT OF SMALL ENTITY STATUS AND REQUEST FOR REFUND  
UNDER 37 C.F.R. §1.28(a)

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

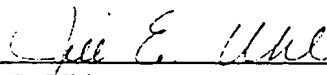
Submitted herewith is a Verified Statement Claiming Small Entity Status (Nonprofit Organization) on behalf of the assignee, ARCH Development Corporation.

A copy of the assignment of this application and the invention thereof to ARCH Development Corporation is attached hereto.

The \$1,558.00 for the above-identified application was paid February 16, 1999. A refund of \$334.00 is requested in view of the small entity status of the assignee. The requested refund should be directed to the undersigned's law firm at the address given below.

Respectfully submitted,

MARSHALL, O'TOOLE, GERSTEIN,  
MURRAY & BORUN

By   
Jill E. Uhl  
Reg. No. 43,213  
Attorneys for Applicants  
6300 Sears Tower  
233 South Wacker Drive  
Chicago, Illinois 60606-6402  
(312) 474-6300

April 7, 1999

**PATENT**

Attorney's Docket No: 27373/35172

Applicant or Patentee: Di Rienzo, et al.  
Serial or Patent No: 09/251,274  
Filed or Issued: February 16, 1999  
For: METHOD FOR DETECTION OF PROMOTER  
POLYMORPHISM IN A UGT GENE PROMOTER.

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY  
STATUS (37 CFR 1.9(f) and 1.27(d)) -- NONPROFIT ORGANIZATION**

I hereby declare that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF ORGANIZATION: ARCH DEVELOPMENT CORPORATION

ADDRESS OF ORGANIZATION: 5640 S. Ellis, Suite 405, Chicago, Illinois 60637

**TYPE OF ORGANIZATION**

- ☐ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION
- ☒ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) and 501(c)(3))
- ☐ NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA
- (NAME OF STATE \_\_\_\_\_)  
(CITATION OF STATUTE \_\_\_\_\_)
- ☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501 (a) and 501 (c)(3)) IF LOCATED IN THE UNITED STATES OF AMERICA
- ☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA
- (NAME OF STATE \_\_\_\_\_)  
(NAME OF STATUTE \_\_\_\_\_)

I hereby declare that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 CFR 1.9(e) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code with regard to the invention entitled Method For Detection Of Promoter Polymorphism In A UGT Gene Promoter, by inventor Anna Di Rienzo, Lalitha Iyer and Mark Ratain described in

- ☐ The specification filed herewith.
- ☒ Application Serial No. 09/251,274, filed February 16, 1999.
- ☐ Patent No. \_\_\_\_\_, issued \_\_\_\_\_.

I hereby declare that rights under contract or law have been conveyed to and remain with the nonprofit organization regarding the above-identified invention. If the rights held by the nonprofit organization are not exclusive, each individual, concern or organization having rights in the invention is listed below, and must file separate verified statements averring to their status as small entities and that no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c), if that person made the invention, or by any concern that would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

FULL NAME: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

☐ INDIVIDUAL      ☐ SMALL BUSINESS CONCERN      ☐ NONPROFIT ORGANIZATION

FULL NAME: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

☐ INDIVIDUAL      ☐ SMALL BUSINESS CONCERN      ☐ NONPROFIT ORGANIZATION

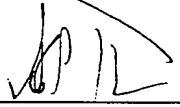
I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: Alan Thomas

TITLE IN ORGANIZATION: Assistant Secretary

ADDRESS OF PERSON SIGNING: 5640 S. Ellis, Suite 405, Chicago, IL 60637

SIGNATURE:  \_\_\_\_\_

Date: 4/1/99

# DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY

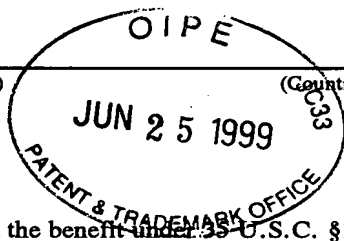
As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name; I believe that I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled "METHOD FOR DETECTION OF PROMOTER POLYMORPHISM IN A UGT GENE PROMOTER," the specification of which was filed on February 16, 1999 as Application Serial No. 09/251,274. I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose to the Patent and Trademark Office all information known to me to be material to patentability as defined in 37 C.F.R. §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

		Priority Claimed	
		<input type="checkbox"/>	<input type="checkbox"/>
		Yes	No

	(Country)	(Day/Month/Year Filed)
(Application Serial Number)		



I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below:

	(Day/Month/Year Filed)
(Application Serial Number)	

I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s) or PCT international application(s) designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior application(s) in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose to the Office all information known to me to be material to patentability as defined in 37 C.F.R. §1.56 which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

	(Day/Month/Year Filed)	(Status-Patented, Pending or Abandoned)
(Application Serial Number)		

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

**POWER OF ATTORNEY:** I hereby appoint as my attorneys, with full powers of substitution and revocation, to prosecute this application and transact all business in the Patent and Trademark Office connected herewith:

Alvin D. Shulman (19,412)  
Allen H. Gerstein (22,218)  
Nate F. Scarpelli (22,320)  
Edward M. O'Toole (22,477)  
Michael F. Borun (25,447)  
Trevor B. Joike (25,542)  
Timothy J. Vezeau (26,348)

Carl E. Moore, Jr. (26,487)  
Richard H. Anderson (26,526)  
Patrick D. Ertel (26,877)  
James P. Zeller (28,491)  
William E. McCracken (30,195)  
Richard A. Schnurr (30,890)  
Anthony Nimmo (30,920)

Christine A. Dudzik (31,245)  
Jeffrey S. Sharp (31,879)  
Martin J. Hirsch (32,237)  
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Richard M. La Barge (32,254)  
Karl A. Vick (33,288)  
Li-Hsien Rin-Laures, M.D. (33,547)

Douglass C. Hochstetler (33,710)  
Robert M. Gerstein (34,824)  
David W. Clough (36,107)  
Richard A. Brandon (37,051)  
Roger A. Heppermann (37,641)  
David A. Gass (38,153)

Send correspondence to: Jill E. Uhl

FIRM NAME	PHONE NO.	STREET	CITY & STATE	ZIP CODE
Marshall, O'Toole, Gerstein, Murray & Borun	312-474-6300	6300 Sears Tower 233 South Wacker Drive	Chicago, Illinois	60606-6402

Full Name of First or Sole Inventor <b>Anna Di Rienzo</b>	Citizenship <b>Italy</b>
Residence Address - Street <b>5410 Blackstone Avenue</b>	Post Office Address - Street <b>5410 Blackstone Avenue</b>
City (Zip) <b>Chicago 60615</b>	City (Zip) <b>Chicago 60616</b>
State or Country <b>Illinois</b>	State or Country <b>Illinois</b>
Date <input checked="" type="checkbox"/> <b>6-9-1999</b>	Signature <input checked="" type="checkbox"/> <i>Anna Di Rienzo</i>

Second Joint Inventor, if any <b>Lalitha Iyer</b>	Citizenship <b>India</b>
Residence Address - Street <b>1208D Federal Street</b>	Post Office Address - Street <b>1208D Federal Street</b>
City (Zip) <b>Chicago 60605</b>	City (Zip) <b>Chicago 60605</b>
State or Country <b>Illinois</b>	State or Country <b>Illinois</b>
Date <input checked="" type="checkbox"/>	Signature <input checked="" type="checkbox"/>

Third Joint Inventor, if any <b>Mark J. Ratain</b>	Citizenship <b>United States of America</b>
Residence Address - Street <b>1040 W. Oakdale</b>	Post Office Address - Street <b>1040 W. Oakdale</b>
City (Zip) <b>Chicago 60657</b>	City (Zip) <b>Chicago 60657</b>
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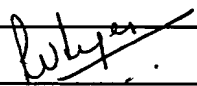
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Date <input checked="" type="checkbox"/>	Signature <input checked="" type="checkbox"/>

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Residence Address - Street <b>1208D Federal Street</b>	Post Office Address - Street <b>1208D Federal Street</b>
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State or Country <b>Illinois</b>	State or Country <b>Illinois</b>
Date <input checked="" type="checkbox"/> <b>June 22, '99</b>	Signature <input checked="" type="checkbox"/> 

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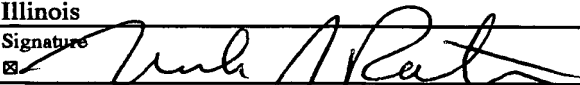
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State or Country <b>Illinois</b>	State or Country <b>Illinois</b>
Date <input checked="" type="checkbox"/> <b>6/8/99</b>	Signature <input checked="" type="checkbox"/> 

## APPLICABLE RULES AND STATUTES

### 37 CFR 1.56. DUTY OF DISCLOSURE - INFORMATION MATERIAL TO PATENTABILITY (Applicable Portion)

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentability defines, to make sure that any material information contained therein is disclosed to the Office.

Information relating to the following factual situations enumerated in 35 USC 102 and 103 may be considered material under 37 CFR 1.56(a).

### 35 U.S.C. 102. CONDITIONS FOR PATENTABILITY: NOVELTY AND LOSS OF RIGHT TO PATENT

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
- (c) he has abandoned the invention, or
- (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraph (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or
- (f) he did not himself invent the subject matter sought to be patented, or
- (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

### 35 U.S.C. 103. CONDITIONS FOR PATENTABILITY; NON-OBVIOUS SUBJECT MATTER (Applicable Portion)

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

### 35 U.S.C. 112. SPECIFICATION (Applicable Portion)

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.